

REMARKS

Applicant respectfully requests consideration of this application.

Office Action Rejections Summary

Claims 1 – 5 have been rejected to under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,941,473 to Tenerz et al. (hereinafter "Tenerz"). Claims 6 – 8, 9, and 22 – 25 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Tenerz. Claims 11 – 17 and 19 – 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tenerz in view of U.S. Patent 5,980,471 to Jafari (hereinafter "Jafari") and U.S. Patent 6,458,088 to Hurtak (hereinafter "Hurtak").

Status of Claims

Claims 1 – 28 remain pending in the application. Claims 1, 6, 22, and 24 have been amended. The amended claims are supported by the specification and no new matter has been added. No claims have been canceled. No new claims have been added.

Rejections under 35 U.S.C. § 102(b)

Claims 1 – 5 have been rejected to under 35 U.S.C. § 102(b) as being anticipated by Tenerz. Applicant submits that claims 1 – 5 are patentable over Tenerz.

Amended independent claim 1 provides:

An apparatus comprising:

a therapeutic guidewire having a high strength proximal core section and flexible distal core section, ***the flexible distal core section having a tapered length and a distal plunge-ground length***; and
at least one optical fiber disposed through the therapeutic guidewire, the optical fiber configured to provide diagnostic information before, during, and after a therapeutic treatment. (emphasis added)

Tenerz discloses a miniaturized sensor placed near the distal end of a guidewire. In particular, Tenerz includes the following disclosure:

The pressure sensor 1 is mechanically connected, for example, by a welded joint 10 or by brazing to a sleeve 5, which comprises a helically wound metal wire in the depicted embodiment. In this region the guide wire will be easily flexible and resilient, which is necessary to avoid the risk for perforating vascular walls when the guide wire is inserted. The easily flexible part is usually 5-20 cm long and merges into a stiffer part towards its proximal end. The stiffer part may comprise a more tightly wound wire, or one that is thicker and thereby stiffer, or a thin-walled metal tube as illustrated in FIG. 1. The junction 8 between easily flexible and stiff portions can be abrupt or it can take place gradually. An advantage from the reliability and safety aspects is obtained when the parts 5 and 6 are fabricated from a single metal piece by mechanical processing, etching, shaping in some other way, etc. The distal end of the pressure sensor is connected to a further region of a helically shaped wire 18 with the aid of a welded joint 20 or by brazing.

(Tenerz, col. 2, lines 22 – 41, and FIG. 1)

As such, nothing in Tererz discloses that the flexible part includes any structural changes such as a tapered length or a plunge-ground length.

In contrast, amended independent claim 1 includes the limitation of “the flexible distal core section having a tapered length and a distal plunge-ground length.” Therefore, Applicant respectfully submits that claim 1 is not anticipated by Tererz under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claims 2 – 5 depend either directly or indirectly from independent claim 1, and thus include the limitation of “the flexible distal core section having a tapered length and a distal plunge-ground length.” As such, Applicant respectfully submits that claims 2 – 5 are also not anticipated Tererz under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Rejections under 35 U.S.C. § 103

Claims 6 – 8, 9, and 22 – 25 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Tenerz. Applicant respectfully submits that claims 6 – 8, 9, and 22 – 25 are patentable over Tenerz.

Amended independent claim 6 provides:

An apparatus comprising:

a therapeutic guidewire having a high strength proximal core section and flexible distal core section, ***the flexible distal core section having a tapered length and a distal plunge-ground length***, the therapeutic guidewire configured to operatively receive a treatment device;

a polymeric jacket disposed about the distal core section; and
at least one optical fiber disposed within the therapeutic guidewire to sense vessel and blood characteristics. (emphasis added)

Amended independent claim 22 provides:

A system for sensing vessel and blood characteristics, the system comprising:

a data processing system; and

an apparatus coupled to the data processing system, the apparatus comprising a therapeutic guidewire having a high strength proximal core section and flexible distal core section and at least one optical fiber disposed therein, ***the flexible distal core section having a tapered length and a distal plunge-ground length***, the optical fiber capable to sense vessel and blood characteristics. (emphasis added)

Amended independent claim 24 provides:

A method of sensing vessel and blood characteristics, the method comprising:

inserting an apparatus into a vasculature of a patient, the apparatus comprising a therapeutic guidewire having a high strength proximal core section and flexible distal core section and at least one optical fiber disposed therein, ***the flexible distal core section having a tapered length and a distal plunge-ground length***, the optical fiber configured to provide diagnostic information before, during, and after the therapeutic treatment;

advancing the apparatus to a desired location in the vasculature; operating a data processing system coupled to the apparatus such that light signals are transmitted to the desired location in the vasculature and reflected light signals are collected by the data processing system; and

processing the reflected light signals to provide vessel and blood characteristics. (emphasis added)

As discussed above, nothing in Tenerz discloses or suggests that the flexible part includes any structural changes such as a tapered length or a plunge-ground length. Applicant respectfully submits that Tenerz does not

disclose all the limitations of amended independent claims 6, 22, and 24. In particular, Tenerz does not include the limitation of "the flexible distal core section having a tapered length and a distal plunge-ground length."

Applicant also submits that there is no motivation in Tenerz to include a tapered length and a plunge-length for the flexible part. In particular, a tapered flexible part would be too small to contain the pressure sensor described by Tenerz. As such, applicant respectfully submits that claims 6, 22, and 24 are patentable over Tenerz under 35 U.S.C. § 103(a), and request removal of the rejection. Claims 7 – 9 depend from claim 6, and claim 23 depends from claim 22. As such, claims 7 – 9 and 23 each include the limitation of "the flexible distal core section having a tapered length and a distal plunge-ground length." Accordingly, claims 7 – 9 and 23 are also patentable over Tenerz under 35 U.S.C. § 103(a).

Claims 11 – 17 and 19 – 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tenerz in view of Jafari and Hurtak. Claims 11 – 17 and 19 – 21 depend either directly or indirectly from claim 6 and thus each includes the limitation of "the flexible distal core section having a tapered length and a distal plunge-ground length." As discussed above, nothing in Tenerz discloses or suggests this limitation. Jafari discloses a guidewire disposed within a catheter. In particular, Jafari includes the following disclosure:

The distal core portion 12 has at least one tapered section 21 which becomes smaller in the distal direction. A helical coil 22 is disposed about the distal core section 12 and is secured by its distal end to the distal end of shaping ribbon 23 by a mass of solder which forms rounded plug 24 when it solidifies. The proximal end of the helical coil 22 is secured to the distal core section 12 at a proximal location 25 and at intermediate location 26 by a suitable solder.

(Jafari, col. 6, lines 14 – 22, and FIG. 1)

Nothing in Jafari discloses that the distal core portion includes a distal plunge-ground length in addition to a distal taper length. As such, Jafari fails to cure the deficiency of Tenerz.

Hurtak discloses a medical guidewire for use with MR systems. In particular, Hurtak includes the following disclosure:

The distal tip portion 3 of the guidewire 1 may be formed of a glass or plastic, as shown in FIG. 2, or of a metal as shown in FIGS. 8-13. The outer diameter of guidewire 1 preferably tapers to a smaller diameter toward the distal tip, as illustrated in FIGS. 8-13. The metal tip portion may be a material having a selected magnetic susceptibility, such as stainless steel, nickel titanium (nitinol), or tantalum. Preferably, the length of the metal distal tip segment is substantially shorter than the wavelength of the magnetic resonance field in which the guidewire is used.

(Hurtak, col. 3, lines 60 – 67, and FIGS. 8 – 13)

Nothing in Hurtak discloses that the distal core portion includes a distal plunge-ground length in addition to a distal taper length. As such, Hurtak fails to cure the deficiencies of Tenerz or Jafari.

Applicants respectfully submit that there is no motivation to combine Tenerz, Jafari, and Hurtak. The Office Action states that it would have been obvious to a person of ordinary skill in the art “to have a movable optical fiber or a fiber being exposed to the vasculature of the patient because either configuration satisfies the measurement of blood pressure in any desire[d] vascular location as taught by Tenerz et al. (Office Action dated 11/04/04, page 4). Here, the Office Action merely states an advantage of substituting the guidewire of Jafari or Hurtak, without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.

Even if Tenerz, Jafari, and Hurtak were somehow combined, the combination would still not include all the limitations of amended independent claim 6. In particular, the

combination would not include the limitation of "the flexible distal core section having a tapered length and a distal plunge-ground length." As such, applicant respectfully submits that claim 6 is patentable over Tenerz, Jafari, and Hurtak under 35 U.S.C. §103(a).

Claims 11 – 17 and 19 – 21, which depend from claim 6, include the limitation of "the flexible distal core section having a tapered length and a distal plunge-ground length." As such, applicant respectfully submits that claims 11 – 17 and 19 – 21 are also patentable over Tenerz, Jafari, and Hurtak under 35 U.S.C. §103(a) and request removal of the rejection.

In conclusion, Applicants respectfully submit that in view of the amendments and arguments set forth herein, the applicable rejections have been overcome.

If the allowance of these claims could be facilitated by a telephone conference, the Examiner is invited to contact Suk Lee at (408) 720-8300. If there are any additional charges, please charge our Deposit Account No. 02-2666.

Respectfully submitted,

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